

User Manual

Water Bottle, Cap, & Tubing Set: Reusable SCT-468



Water Bottle, Cap, & Tubing w/CO₂ Set: Reusable SCT-469



AUTOCLAVABLE

Part Number FSE-058-EN-1.0

Released February, 2014.

Rx Only

Caution: Federal U.S. law restricts this device to sale by or on the order of a physician.



IMPORTANT: Read this User Manual in its entirety prior to using the Reusable Water Bottle.

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DISCLAIMER

EndoChoice, Inc. shall not be obligated in any manner in respect to bodily injury and/or property damage arising from the use of the device if such use is not in strict compliance with instructions and safety precautions contained in the relevant operating manuals and in all supplements thereto, in all product labels, and according to all terms of warranty and sale of this device, or in any change not authorized by EndoChoice, Inc.



WARNING

- User provided ancillary equipment and/or accessories are NOT validated or warranted by EndoChoice, Inc. The use of such user provided items is the sole responsibility of the party using such items.**

	<table border="1"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP
EC	REP		
EndoChoice, Inc. 11810 Wills Rd. Alpharetta, GA 30009 Tel: 770-682-8700 Fax: 866-567-8218 Email: customercare@EndoChoice.com	Atlantico Systems, Ltd.34 OldfieldKingston, Galway, Ireland Tel: +35391443609 Email: info@atlanticosystems.com		

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Safety Information – Please Read Prior to Use

Using this manual

This manual provides information required to enable you to use the Water Bottle, Cap, & Tubing Set - reusable SCT-468, or Water Bottle, Cap, & Tubing w/CO₂ Set – reusable SCT-469. Read this manual thoroughly before using the device and ensure that you understand the proper use of and care for the device. If you have any questions or comments regarding the use of the device, please contact EndoChoice, Inc.

The following conventions are used in this manual:

Symbol	Description
 WARNING	A warning is a statement that alerts / indicates a potentially hazardous situation associated with the use or misuse of the device, which, if not avoided, could result in serious injury or death.
CAUTION:	A caution is a statement that alerts / indicates a potentially hazardous situation associated with its use or misuse which may, if not avoided, result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
	An informational note provides additional information of interest to the user.

Support

Outside the United States	United States
EndoChoice GmbH Otto-Hahn-Str. 11 25337 Elmshorn Germany	EndoChoice, Inc. 11810 Wills Rd. Alpharetta, GA 30009
+49 (0) 4121-649390 Phone +49 (0) 4121-649383 Fax	888-682-ENDO (3636) Phone 866-567-8218 Fax

Summary of device symbols

Symbol	Description
	Consult instructions for use
	Caution
	Manufacturer
	Catalog number
	Must not be disposed of as unsorted municipal waste but should be collected separately.
	Number of units
	CE Mark (Class IIa)
	European Representative
	Federal US law restricts this device for sale by or on the order of a physician.
	Non-sterile
	Date of Manufacture
	Manufactured according to Restriction of Hazardous Substances Directive

Safety Guidelines – please read prior to use

- This product was designed and manufactured to meet all safety requirements applicable to medical ancillary equipment. However, anyone operating the device must be fully aware of the potential safety hazards. It should be operated and maintained in strict compliance with the safety precautions and operating instructions contained herein.
- The device is not to be modified in any way. Any attempt to disassemble, repair, or modify this device by anyone other than an EndoChoice authorized service technician presents

risk to the patient or operator and may result in equipment damage. Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than EndoChoice's own authorized service personnel is excluded from EndoChoice's warranty and is not warranted by EndoChoice in any way.

- Do not use the device if unsafe conditions exist.
- This device does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result.
- This device is compatible with the Fuse™ Endoscope system. Using incompatible equipment can result in patient injury and/or equipment damage.

User Qualification – please read prior to use

- The operator of this device must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.
- The manufacturer or vendor of the equipment makes no claim that the act of reading this manual renders the reader qualified to operate the device.
- It is important that this manual remain available, studied carefully, and reviewed periodically by the authorized operators.

Warnings and cautions

Follow the warnings and cautions given below when handling this device. This information is to be supplemented by the warnings and cautions provided in each chapter.



WARNING

- This device was not high-level disinfected or sterilized before shipment. Before using this device for the first time, reprocess it according to the instructions given in CHAPTER 6, “**Reprocessing**”. After using this device, reprocess and store it according to the instructions given in CHAPTER 6, “**Reprocessing**” and CHAPTER 7, “**Storage**”. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

CAUTION:

- *Do not bend, twist or pull the tube excessively. The tube could become damaged, which could make air and/or water feeding impossible.*

Reprocessing

- After use, reprocess and store according to the instructions given in CHAPTER 6, “**Reprocessing**” and CHAPTER 7, “**Storage**”. Improper and/or incomplete reprocessing or

Safety Information – Please Read Prior to Use

storage can create an infection control risk, cause equipment damage, or reduce performance.

- Separate reprocessing of the Water Bottle Reprocessing Adaptor (EndoChoice Part Number FSR-4368) is not required prior to the reprocessing of the Reusable Water Bottle.

CHAPTER 1 Regulatory Information

1.1 Intended use

The Reusable Water Bottle is designed to be used with EndoChoice Fuse™ endoscopes to allow gas insufflation and sterile water feeding during endoscopic procedures.

The Reusable Water Bottle with CO2 Tubing is designed to be used with EndoChoice Fuse™ endoscopes to allow CO2 insufflation and sterile water feeding during endoscopic procedures.

Do not use this device for any purpose other than its intended use.

1.2 USA regulations

CAUTION:

- *Federal U.S. law restricts this device to sale by or on the order of a physician.*

1.3 CE conformity



CE 0086

EC	REP
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EndoChoice Inc. 11810 Wills Road
Alpharetta, GA 30009 USA
Tel: 888-682-3636
Email: customercare@EndoChoice.com

Atlantico Systems Ltd.
34 Oldfield
Kingston, Galway, Ireland
Tel: +35391443609
Email: info@atlanticosystems.com

This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class IIa.

In the European Union, the following symbol indicates that when the last user wishes to discard this product, it must be sent to appropriate facilities for recovery and recycling. Contact your local EndoChoice representative for additional information on the collection and recovery programs available for this product.



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CHAPTER 2 Device Overview

The following table provides catalog and model numbers for the Reusable Water Bottle Sets, and a separately available adaptor.

Table 1. Reusable Water Bottle Catalog Numbers

Catalog Number	Description
SCT-468	Water Bottle, Cap, and Tubing Set, Reusable <ul style="list-style-type: none"> • Water Bottle • O-Ring • Water Tube • Water Bottle Cap • Tube with Tube Connector • Water Bottle Reprocessing Adaptor*
SCT-469	Water Bottle, Cap, and Tubing Set with CO ₂ , Reusable <ul style="list-style-type: none"> • Water Bottle • O-Ring • Water Tube • Water Bottle Cap • Tube with Tube Connector • Water Bottle Reprocessing Adaptor* • CO₂ Port and Cap
FSR-4368	Water Bottle Reprocessing Adaptor

* Also available separately (EndoChoice Part Number FSR-4368).

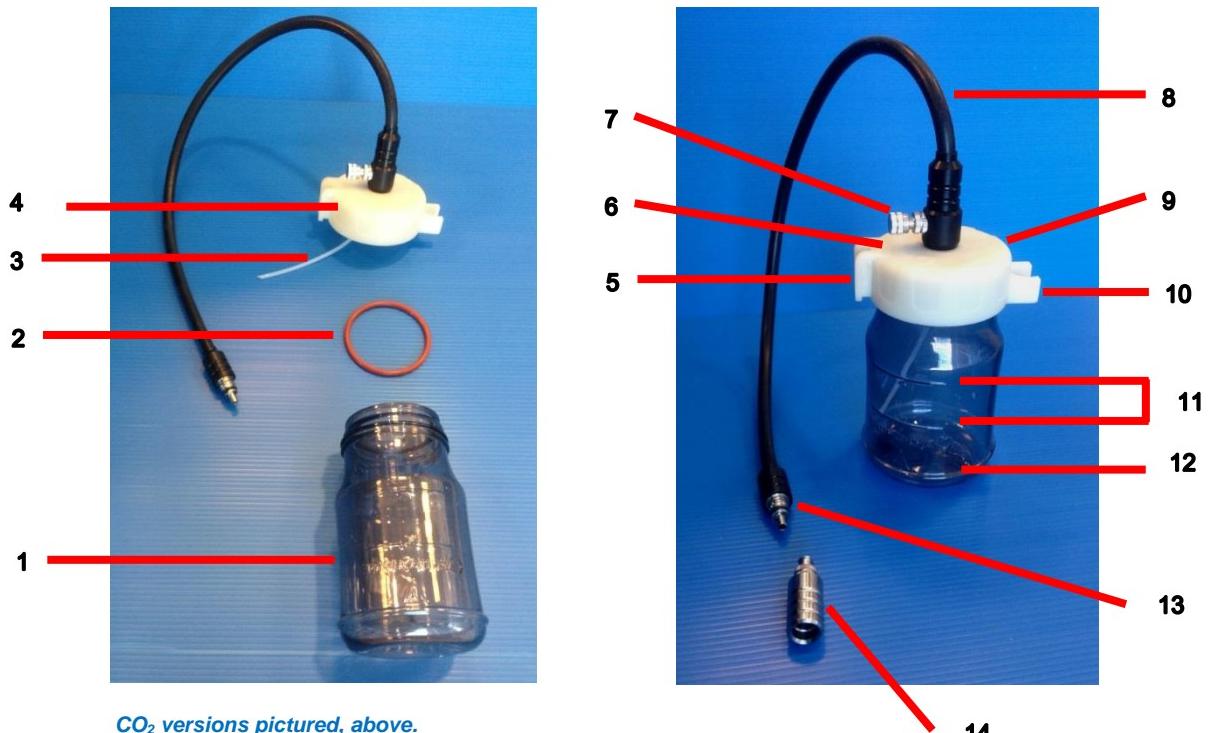
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CHAPTER 3 Device Components

3.1 Packaged Components

Match all items in the package with the components shown below. Inspect each item for damage. If the device is damaged, a component is missing or you have any questions, do not use the device; immediately contact EndoChoice, Inc.

This device was not high-level disinfected or sterilized before shipment. Before using the device for the first time, reprocess it according to the instructions given in CHAPTER 6, "Reprocessing".



CO₂ versions pictured, above.

Item #	Name of Item
1	Water Bottle
2	O-Ring
3	Water Tube
4	Cap
5	Bottle Hanger
6	CE Mark
7	CO ₂ Port and Cap
8	Tube

Device Components

9	Water Bottle Cap
10	Connector Hanger
11	Water Level Marks
12	Lowest Water Level Line
13	Tube Connector
14	Water Bottle Reprocessing Adaptor

3.2 Specifications

3.2.1 Reusable Water Bottle

Description	Details
Capacity	220 ml (filled to marked line)
Medical Devices Directive	This device complies with the requirements of Directive 93/42/EEC concerning medical devices

3.2.2 Environment

Environment	Value
Operating Conditions	
Ambient Temperature	+ 5C (41F) +40C (104F)
Relative Humidity	85% Max RH

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CHAPTER 4 Preparation and Inspection

This chapter provides an overview of the system's setup, and instructions for system preparation and inspection.



WARNING

- Before each procedure, prepare and inspect this device as instructed below. Inspect other equipment to be used with this device as described in the respective instruction manuals. Should the slightest irregularity be suspected, do not use this device; contact EndoChoice. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.
- This device was not high-level disinfected or sterilized before shipment. Before using this device for the first time, reprocess it according to the instructions given in CHAPTER 6, "Reprocessing". Failure to do so could pose an infection control risk and cause tissue irritation.

CAUTION:

- Never drop the Water Bottle or subject it to impacts. The bottle could become damaged, which could make air and/or water feeding impossible.
- The Water Bottle is a consumable item. If inspection of the Water Bottle reveals any irregularities, use a new Water Bottle.
- Do not bend, twist or pull the tube excessively. The tube could become damaged, which could make air and/or water feeding impossible.
- The water bottle O-ring (HPG-4002) is subject to wear over time. If damage or deformation is detected please contact EndoChoice or its representative to order a replacement. To remove the O-ring, pull out the portion that lies in the notch along the bottle's rim (see Figure 1). Attempting to pry the O-ring out of its groove could damage the O-ring.

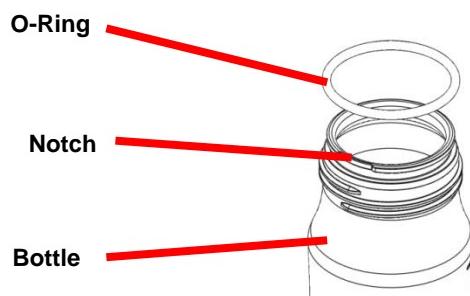


Figure 1.

4.1 Prepare and Inspect the Water Bottle

1. Referring to Section 3.1, "Packaged Components", inspect the Water Bottle and all of its components. Confirm that all components are free of damage or irregularities.
2. When insufflating with CO₂, prepare medical grade CO₂ insufflation system suitable for GI endoscopic procedures in accordance with their respective instruction manuals.



WARNING

- Never fill in the bottle with sterile water while holding it over electrical equipment. If water is spilled on or into the equipment, electrical shock or damage can result.
- Use sterile water only. Using non-sterile water can result in growth of bacteria or channels clogging; this could pose an infection control risk and tissue irritation.
- 3. Fill the bottle with sterile water until the water level is within the water level lines specified on the outside of the bottle to ensure adequate water feeding to the scope.

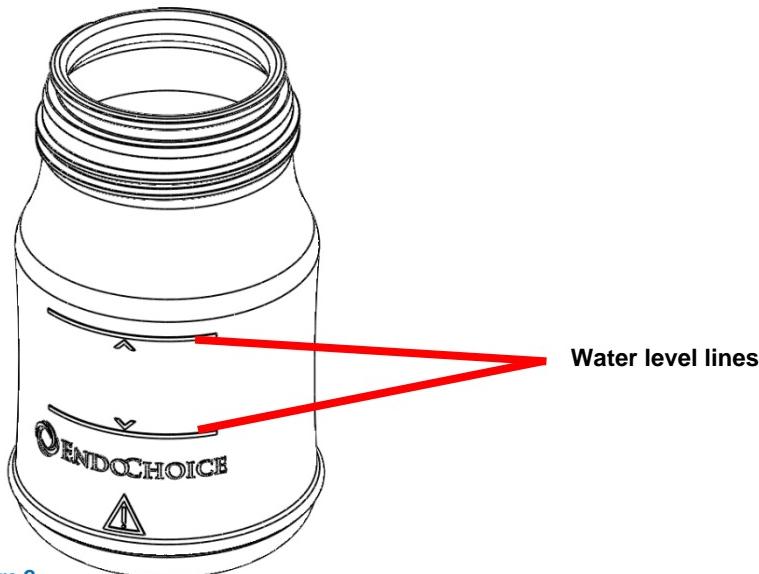


Figure 2.

CAUTION:

- If the O-ring is not correctly attached and the cap is not closed properly, gas insufflation and water feeding may not be possible (see Figure 3).
4. Attach the cap to the bottle. Screwing the cap onto the bottle, the torque for screwing will increase when the O-ring is engaged. From that point, screw the cap an additional 180°.

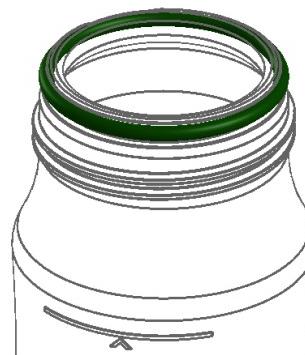


Figure 3.

4.2 Connection to the endoscope

CAUTION:

- Hang the Water Bottle on the Water Bottle Holder of the FuseBox™ or onto the side of the EndoCart using the supplied mounting kit.. Otherwise, the Water Bottle may fall and sterile water could be spilled on surrounding equipment. This could result in equipment damage and/or malfunction.
- Connect the Tube Connector slowly and carefully. Otherwise, the Tube Connector could become damaged, which could make gas insufflation and water feeding impossible.
- When insufflating with CO₂, turn OFF the AIR FLOW from the FuseBox™ to stop air feeding. If the air feeding is not turned off, a gas mixture of nonflammable gas will be insufflated into the body cavity of the patient.
- When insufflating with CO₂, an appropriate insufflator must be used. Do not attempt to connect the device directly to a CO₂ tank.
- If using the CO₂ bottle (SCT-469) and not insufflating with CO₂, make sure that the CO₂ port cap is securely screwed on the port.
 1. Hang the Water Bottle on the Water Bottle Holder of the FuseBox™.
 2. Push the Tube Connector gently onto the air/water port on the endoscope (see Figure 4).

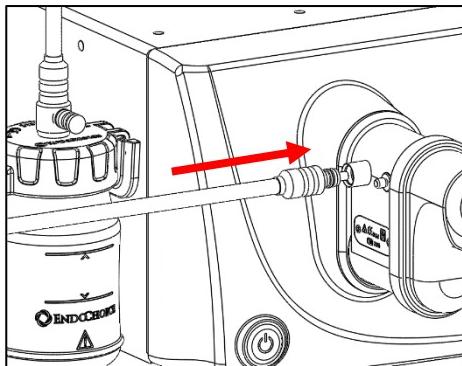


Figure 4.

4.2.1 If insufflating with CO₂

1. Unscrew CO₂ port cap.
2. Securely connect the CO₂ tube from the CO₂ insufflator to the CO₂ port on the Water Bottle.
3. Turn the FuseBox™ ON and set the AIR FLOW on the FuseBox™ to OFF. Confirm that no air is being fed from the FuseBox™.
4. Operate CO₂ insufflation per manufacturer instructions.

4.2.2 Disconnection from the scope

1. Pull the connector from its connection to the air/water port on the endoscope.
2. Hang the connector on the connector hanger on the cap (see Figure 5).

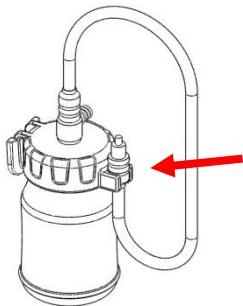


Figure 5.

CHAPTER 5 Operation

The operator of this device must be a physician or a physician-supervised clinician who is well trained and capable of performing the planned endoscopic procedure.

This manual describes only basic procedures and precautions related to the operation of the Water Bottle. This manual does not explain or discuss clinical endoscopic procedures.



WARNING

- At a minimum, clean and high-level disinfect or sterilize the Water Bottle once per day. Failure to do so can result in increased patient infection risk, tissue irritation, device contamination, degraded performance, or loss of functionality. Using Water Bottles that have either been improperly or incompletely reprocessed or stored may cause cross-contamination or infection.
- If insufflating with CO₂ and using a CO₂ bottle, the gas is normally emitted through the small hole in the endoscope's air/water valve. To prevent oxygen deficiency, ensure adequate ventilation.

CAUTION:

- Before insufflating with CO₂, turn OFF the FuseBox™ Air Flow to disable air feeding. If the air flow remains ON, an air and gas mixture will continue to insufflate into the patient's body cavity.
 - Monitor the water level carefully during the procedure and fill the Water Bottle with sterile water as necessary. Water feeding will stop when the water level falls below the lowest water level line.
- 1. Perform gas insufflation and water feeding as described in the respective instruction manuals for the gas/water valve and Fuse™ endoscope being used with this Water Bottle.
 - If the water level falls below the lowest water level line during use, disconnect the Water Bottle's Tube Connector from the endoscope as described in Section 4.2.2, "Disconnection from the scope". Then, refer to CHAPTER 4, "Preparation and inspection", to learn how to refill the Water Bottle with sterile water.

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CHAPTER 6 Reprocessing



WARNING

- The Water Bottle was not high-level disinfected or sterilized before shipment. Before first time use, reprocess the Water Bottle according to the instructions given in this Chapter.

6.1 General policy

- It is strongly recommended that reprocessing personnel:
 - have a thorough understanding of patient cross contamination resulting from improper cleaning and disinfection or sterilization, and
 - follow the official standards defined by the hospital's administrators or other national or local official institutions.
- A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
 - Your institution's reprocessing procedures
 - Occupational health and safety regulations
 - All national and local hospital guidelines and policies
 - The instructions in this manual
 - The mechanical aspects of endoscopic equipment
 - Pertinent germicide labeling



WARNING

- At a minimum, clean and high-level disinfect or sterilize the Water Bottle once per day. Failure to do so can result in increased patient infection risk, tissue irritation, device contamination, degraded performance, or loss of functionality. Using Water Bottles that have either been improperly or incompletely reprocessed or stored may cause cross-contamination or infection.
- Wear personal protective equipment to guard against dangerous reprocessing chemicals and potentially infectious material, such as patient debris.
- During cleaning, high-level disinfection and sterilization, protect your skin by wearing personal protective equipment, such as properly fitted protective (chemical-resistant) gloves, eyewear, face mask, and moisture-resistant clothing.
- Always remove contaminated protective clothing before leaving the reprocessing area.

6.2 Compatible Reprocessing Methods and Chemical Agents

6.2.1 Compatibility Summary

Several methods of reprocessing are compatible with EndoChoice endoscopic equipment. Certain components and accessories, however, are incompatible with some methods, which can cause equipment damage.

For appropriate reprocessing methods, refer to:

- the table below,
- the recommendations of your hospital's infection control committee, and
- all national and local hospital guidelines and policies.

Table 2. Water Bottle Reprocessing Type Compatibility Summary

Environment	Effect	Water Bottle Compatibility
Detergent solution (such as Pure by EndoChoice)	Cleaning	Compatible
High-Level Disinfection solution (such as Cidex OPA)	High-level disinfection	Compatible
ETO gas sterilization	Sterilization	Not Compatible
Steam sterilization (autoclave)	Sterilization	Compatible
Ultrasonic cleaning	Cleaning	Not Compatible



WARNING

- **Do not reuse detergent solution; tissue irritation or infection control risk may result.**
- **Keep detergent foaming to a minimum. Excessive detergent foaming can prevent fluid from adequately contacting internal lumens and may limit the effectiveness of subsequent high-level disinfection or sterilization.**
- **Alcohol is not a sterilant or high-level disinfectant.**

6.3 Required Reprocessing Equipment

The following equipment and materials are required for reprocessing. The items listed below – including cleaning agents (responsible for removal of soil), high-level disinfecting agents (responsible for reduction of microbes) and rinsing water (responsible for removal of agent residuals) – were validated and demonstrated to be compatible with the device and to meet the predefined reprocessing performance criteria.

Replace any of the reusable equipment listed below that shows signs of wear prior to reprocessing.

Table 3. Required Reprocessing Equipment

✓ Equipment	Description	Important
Personal Protective Equipment	Eyewear, facemask, moisture-resistant clothing, and long chemical resistant gloves.	Ensure the reprocessing room is adequately ventilated and lighted.
Clean Lint-Free Cloths	Clean lint-free cloth may be used for all reprocessing steps except the final drying step.	
Sterile Lint-Free Cloths	A new, sterile lint-free cloth MUST be used during final drying step, and it may be used for all reprocessing steps.	
Single-Use Cleaning Brush	A new, non-metal single-use channel Cleaning brush such as: EndoChoice's HedgeHog Double-End Channel Brush (SBD-228-50).	
Detergent Solution	Use a medical grade, low foaming, natural pH or enzymatic detergent indicated for use with flexible endoscopes such as: Pure™ (by EndoChoice). Follow the manufacturer's recommendations, including personal protection to be used, dilution, temperature, immersion duration, storage, date of expiration, disposal, etc.	DO NOT REUSE DETERGENT SOLUTION! Solution should be replaced after being used to reprocess one Water Bottle.
Rinsing Water – Sterile	<ul style="list-style-type: none"> Sterile Water MUST be used for final rinsing step following high-level disinfection. Temperature: 22 - 30 °C (71.6 - 80.6 F) Minimum required volume: 10 Liters 	DO NOT REUSE RINSING WATER! Water should be replaced after being used to reprocess one Water Bottle.
Rinsing Water – Potable Tap	<ul style="list-style-type: none"> Clean potable tap water may be used for all other cleaning steps. Temperature: 22 - 30 °C (71.6 - 80.6 F) Minimum required volume: 10 Liters 	DO NOT REUSE RINSING WATER! Water should be replaced after being used to reprocess one Water Bottle.

✓ Equipment	Description	Important
Water Bottle Reprocessing Adaptor	Reusable adaptor that connects to the Tube Connector; allows connection of a Syringe (Luer Lock). Available from EndoChoice (Part # FSR-4368).	
Syringe (Luer Lock)	Single-use sterile 30 mL syringe – at least 7 units.	
High-Level Disinfectant Solution	Use an FDA-cleared/CE-marked high level disinfectant, like Cidex® OPA (by Advanced Sterilization Products), which has been validated for use in the reprocessing of this device. Follow the manufacturer's recommendations, including personal protection to be used, dilution, temperature, immersion duration, storage, date of expiration, disposal etc.	If the high-level disinfectant solutions are reused, routinely check their efficiency with test strips according to the manufacturer recommendations. Do not use solutions beyond their expiration date. Test high-level disinfectant MEC (Minimal Effective Concentration) routinely.
70% alcohol	Isopropyl should be stored in closed container to avoid evaporation.	Alcohol is not a sterilant or high-level disinfectant. DO NOT REUSE ALCOHOL!
Basins	Containers, sinks, and basins should be large enough to contain the Water Bottle. Minimum recommended basin dimension is 40 cm X 30 cm x 15 cm / 16" x 12" x 6". The basin should have a tight-fitting lid if it is also used for high-level-disinfection. Number of basins required is four (4): (1) Used during Manual Cleaning (Detergent) (1) Used during Manual Cleaning (Water) (1) Used during High-level Disinfection (High-Level disinfectant) (1) Used during Rinsing (Sterile Water)	
Transportation Containers or Pads	It is recommended that the Water Bottle is transported in a closed container or closed transport pad (such as the EndoChoice CinchPad®) to prevent contamination or equipment damage during transport. A 40 cm X 30 cm x 15 cm / 16" x 12" x 6" container may be used.	
Sterilization Wrap	Use a sterilization wrap that is compatible with pre-vacuum steam sterilization with a minimal size of 30 cm x 30 cm (12" x 12").	DO NOT USE A SMALLER STERILIZATION WRAP.

✓ Equipment	Description	Important
Autoclave	Use an autoclave that will operate at the conditions specified in Section 6.5.2, “Steam Sterilization (Autoclave)”. <hr/>	

6.4 Cleaning



WARNING

- Follow the Water Bottle cleaning instructions provided below. Otherwise, effective high-level disinfection or sterilization cannot be achieved. Clean the Water Bottle thoroughly before high-level disinfection or sterilization to remove any microorganisms that could impair high-level disinfection or sterilization efficiency.

CAUTION

- Never drop or subject the Water Bottle to impacts. A damaged Water Bottle may prevent gas insufflation and water feeding.
- Do not bend, twist or pull the tube excessively. A damaged tube may prevent gas insufflation and water feeding.
- Prior to cleaning, high-level disinfection and sterilization, disassemble the Water Bottle as shown in Figure 6, below. Do not disassemble the components further. A damaged Water Bottle may prevent air and/or water feeding.
- The O-ring is an article of consumption. Exchange for a new O-ring when there is a flaw or a transformation in the O-ring. A damaged O-ring may prevent air and/or water feeding.
- To remove the O-ring, pull out the portion of it that lies in the notch along the bottle's rim (see Figure 7). Attempting to pry the O-ring out of its groove could damage the O-ring and/or the bottle.
- Do not bend, pull or twist the water tube on the underside of the cap with excessive force. A damaged water tube may prevent water feeding.
- Never detach the water tube from the cap. Doing so could damage the water tube, preventing water feeding.



Figure 7.

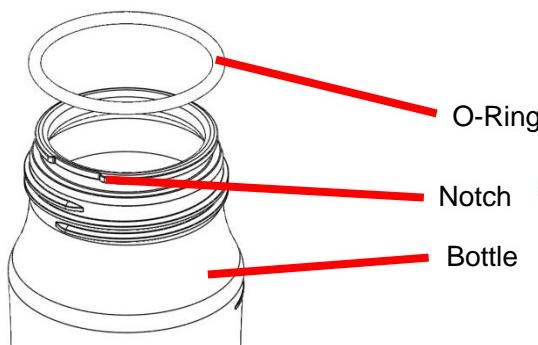


Figure 6.

1. Wear the protective equipment specified in Section 6.3, "Required reprocessing equipment".
2. Washing under running water
 - a. Place the complete, unopened, contaminated Water Bottle in a sink.
 - b. Rinse the bottle's external surfaces under running tap water (22-30°C) using a lint free cloth to remove gross soil for at least 60 seconds.
3. Fill a basin with detergent solution at the temperature and concentration recommended by the detergent manufacturer.
4. Disassemble the bottle components: Bottle, Bottle tubing, O-ring, and if using a CO₂ bottle, unscrew the CO₂ port cap.
5. Cleaning and flushing with detergent solution
 - a. Completely submerge all components in the prepared detergent basin.
 - b. Thoroughly scrub for at least 30 seconds each of the following Water Bottle's parts/locations: interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a clean lint free cloth.
 - c. Thoroughly brush for at least 30 seconds each of the following locations:
 - the threads of the bottle and cap, and
 - at the Tube Connector.
 - d. If using a CO₂ Water Bottle, thoroughly brush CO₂ port and port cap for at least 30 seconds.
 - e. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture, below.



- f. Attach a 30 cc (30 mL) syringe filled with the prepared detergent and inject a total of 120 cc (120 mL) of detergent through the tube.
 - g. Disconnect the Water Bottle Reprocessing Adaptor.
 - h. Allow the Water Bottle to soak in the detergent solution for a minimum of 1 minute at room temperature (22-30°C).
6. Rinsing with water following manual cleaning
 - a. Fill a clean basin with clean potable water.
 - b. Completely submerge all components in the water basin.
 - c. Thoroughly scrub for at least 30 seconds the following Water Bottle's parts/locations: interior, exterior, cap, tube's exterior, O-ring and Tube Connector using clean lint free cloth.

Reprocessing

- d. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the above picture.
 - e. Attach a 30 cc (30 mL) syringe filled with clean potable water and inject a total of 120 cc (120 mL) of water through the tube.
 - f. Disconnect the Water Bottle Reprocessing Adaptor.
- 7. Rinsing with air**
- a. Remove all components from the water basin.
 - b. Thoroughly wipe until dry each of the following Water Bottle's parts/locations: interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a clean, dry, lint free cloth.
 - c. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture above.
 - d. Attach a 30 cc (30 mL) syringe filled with air and inject a total of 120 cc (120 mL) of air through the tube.
 - e. Disconnect the Water Bottle Reprocessing Adaptor.
- 8. When the Water Bottle is thoroughly dry after cleaning, continue with high-level disinfection or sterilization.**

6.5 High-Level Disinfection and Sterilization



WARNING

- **Disassemble the Water Bottle to its parts: the bottle, cap, and O-ring. Otherwise, effective high-level disinfection or sterilization might not be achieved, which would pose an infection control risk or could cause tissue irritation.**

CAUTION

- *Never drop the Water Bottle or subject it to impacts. The bottle could become damaged, which could make gas insufflation and water feeding impossible.*
- *Do not bend, twist or pull the tube excessively. The tube could become damaged, which could make gas insufflation and water feeding impossible.*

6.5.1 High-Level Disinfection



WARNING

- **Rinse the Water Bottle thoroughly and carefully. The Water Bottle must be free of high-level disinfectant and thoroughly flushed with sterile water to avoid the possibility of exposing the next patient to residual high-level disinfectant.**
- **Make sure that the reprocessing area is adequately ventilated as dictated by hospital policy or national occupational health regulation. Adequate ventilation (at least eight to ten air exchanges per hour) will help reduce chemical vapors.**
 1. Wear the protective equipment specified in Section 6.3, "Required Reprocessing Equipment".
 2. Fill a basin with high-level disinfectant solution at the temperature and concentration recommended by the high-level disinfectant manufacturer.
 3. High-level disinfecting and flushing with high-level disinfectant solution
 - a. Completely submerge all components in the high-level disinfectant basin.
 - b. Thoroughly scrub for at least 30 seconds each of the following Water Bottle's parts/locations: interior, exterior, cap, tube's exterior, O-ring and Tube Connector using clean lint free cloth.
 - c. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown below.



- d. Attach a 30 cc (30 mL) syringe filled with high-level disinfectant and inject a total of 120 cc (120 mL) of high-level disinfectant through the tube.
 - e. Disconnect the Water Bottle Reprocessing Adaptor.
 - f. Allow the Water Bottle to soak in the high-level disinfectant solution for the time recommended by the HLD manufacturer.
 - g. Empty the Water Bottle and remove from the high-level disinfectant solution.
4. Rinsing with sterile water following High-Level Disinfection
 - a. Fill a clean basin with a minimum of 2 gallons of sterile water.
 - b. Completely submerge all components in the water basin for at least 1 minute.
 - c. Thoroughly scrub for at least 30 seconds each of the following Water Bottle's parts/locations: the bottle's interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a sterile, lint free cloth.
 - d. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture above.
 - e. Attach a 30 cc (30 mL) syringe filled with sterile water and inject a total of 120 cc (120 mL) of sterile water through the tube.
 - f. Discard rinse water, and repeat steps a – e two more times for a total of 3 rinse cycles.
 - g. Disconnect the Water Bottle Reprocessing Adaptor.
 5. Flushing with air
 - a. Remove all components from the water basin.
 - b. Thoroughly wipe the bottle's interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a sterile, dry lint free cloth.
 - c. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture above.
 - d. Attach a 30 cc (30 mL) syringe filled with air and inject a total of 120 cm³ (120 mL) of air.
 - e. Disconnect the Water Bottle Reprocessing Adaptor.
 6. Rinsing with alcohol
 - a. Thoroughly scrub the bottle's interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a sterile, lint free cloth soaked with alcohol.
 - b. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture above.
 - c. Attach a 30 cc (30 mL) syringe filled with alcohol and inject a total of 120 cc (120 mL) of alcohol.
 - d. Disconnect the Water Bottle Reprocessing Adaptor.
 7. Flushing with air
 - a. Thoroughly wipe dry the bottle's interior, exterior, cap, tube's exterior, O-ring and Tube Connector using a sterile, dry lint free cloth.
 - b. Attach the Water Bottle Reprocessing Adaptor to the Tube Connector as shown in the picture above.
 - c. Attach a 30 cc (30 mL) syringe filled with air and inject a total of 120 cc (120 mL) of air.
 - d. Disconnect the Water Bottle Reprocessing Adaptor.

6.5.2 Steam Sterilization (Autoclave)

Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.



WARNING

- Always leave space between the packages in the autoclave. Packages placed too close together will not achieve effective sterilization.
 - Do not handle wet packages. Allow the packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.
 - Put the O-Ring in position (i.e., on the Water Bottle Cap) BEFORE sterilization to avoid contamination during reassembly prior to usage.
1. Before sterilization, the device must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
 2. Wear the protective equipment as specified in the Table in Section 6.3, "Required Reprocessing Equipment".
 3. Remove the Water Bottle Reprocessing Adaptor from the Tube Connector.
 4. Assemble the O-ring on the Water Bottle Cap prior to steam sterilizing to avoid contamination during reassembly.
 5. If using a CO₂ bottle, unscrew CO₂ port cap.
 6. Wrap all components together in sterilization wrap.
 7. Place the sterilization wrap containing the Water Bottle components in the autoclave and steam sterilize at the conditions given below.
 - For details on operation of the autoclave, refer to the instruction manual for the autoclave.
 8. Allow the sterilization wrap to dry within the autoclave using the autoclave's drying cycle at the conditions given below.

Steam Sterilization

Sterilizer Type: Pre vacuum

Min. Temperature: 132°C (270°F)

Min. Exposure time: 4 Min.

Min. Dry time: 30Min.

The following Steam Sterilization parameters are mandatory in some European countries:

Sterilizer Type: Pre vacuum

Min. Temperature: 134°C (270°F)

Min. Exposure time: 4 Min.

Min. Dry time: 30Min.

The following Steam Sterilization parameters are mandatory in some European countries:

Sterilizer Type: Pre vacuum

Min. Temperature: 134°C (270°F)

Min. Exposure time: 18 Min.

Min. Dry time: 30Min.

 *Do not exceed 140°C (284°F) during sterilization.*

CAUTION

- *Never drop the Water Bottle or subject it to impacts. The bottle could become damaged, which could make gas insufflation and water feeding impossible.*
- *Do not bend, twist or pull the tube excessively. The tube could become damaged, which could make gas insufflation and water feeding impossible.*

CHAPTER 7 Storage



WARNING

- Do not store the device in a damaged, wet or improperly sealed sterile package. An improperly stored device may compromise the sterility of the device, pose an infection control risk and/or cause tissue irritation.
- Do not store sterile packages containing the device in a place where they will become damaged, wet or improperly sealed. An improperly stored device may compromise the sterility of the device, pose an infection control risk and/or cause tissue irritation.

7.1 Inspection before Storage

Prior to storage, inspect the sterile packages as follows:

Confirm that the sterile packages containing the device are free from tears, inadequate sealing or water damage. If tears, inadequate sealing or water damage is detected, repackage and sterilize again as described in CHAPTER 6, "Reprocessing".

7.2 Storage

Store the device in the sterile packages at room temperature in a clean and dry environment. Do not store it in direct sunlight or in the presence of X-rays.

Ensure that the packaged devices are not crushed by surrounding objects during storage. Consult the sterile package manufacturer for any additional storage instruction.

- Always store a sterilized Water Bottle in the sterile packaging.



WARNING

- These storage parameters are not intended to preserve Water Bottle sterility. If necessary, reprocess the Water Bottle again prior to use.



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EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009 USA
Tel: 888-682-3636
Email: customercare@EndoChoice.com

Atlantico Systems Ltd.
34 Oldfield
Kingston, Galway, Ireland
Tel: +35391443609
Email: info@atlanticosystems.com